



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Florida District
555 Winderley Place
Suite 200
Maitland, Florida 32751

Telephone: 407-475-4700
FAX: 407-475-4768

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-01-41

March 6, 2001

Carlos Blas Del Amo, President
Sea Fresh of Miami, Inc.
7580 N.W. 77th Terrace
Medley, Florida 33166

Dear Mr. Del Amo:

On October 31 and November 1, 2000, the Food and Drug Administration (FDA) conducted an inspection of your facility located at the above address. The inspection was conducted to determine your firm's compliance with FDA's seafood processing regulations (21 CFR 123).

During our inspection, the FDA investigator found serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations, some of which were previously brought to your attention, cause the products you import and process to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. The FDA investigator also provided you with a copy of the Domestic Seafood HACCP Report (Form FDA 3501), Importer Seafood HACCP Report (Form FDA 3502) and Inspectional Observations (FDA Form 483), which presents his evaluation of your firm's performance regarding various aspects of the HACCP requirements. The observations of concern to us are as follows:

Import

You must implement an affirmative step which ensures that the fish and fishery product(s) you import are processed in accordance with the seafood HACCP regulation, to comply with 21 CFR 123.12(a)(2)(ii). However, your firm did not perform an affirmative step for the spiny lobster tails manufactured by [REDACTED].

You must have product specifications that are designed to ensure that the fish and fishery products you import are not injurious to health, to comply with 21 CFR 123.12(a)(2)(i). However, your firm does not have product specifications for any of the seafood products you import.

You must implement an affirmative step which ensures that the fish and fishery product(s) you import are processed in accordance with the seafood HACCP regulation, to comply with 21 CFR 123.12(a)(2)(ii). However, your firm performed an affirmative step of maintaining on file a copy of the foreign processor's HACCP plan and a written guarantee for all of the products manufactured by [REDACTED] that was not adequate because:

The [REDACTED] HACCP plan for the grouper and snapper you import does not list the food safety hazard of ciguatera fish poisoning.

The [REDACTED] HACCP plan for fin fish lists critical limits at both of the receiving critical control points that are not adequate to control the histamine hazard, as they do not include a requirement to maintain harvest vessel records and check internal temperatures or perform histamine testing with internal temperature checks for products received directly from the fishermen.

The [REDACTED] HACCP plan for fin fish lists monitoring procedures at the receiving critical control points that are not adequate to control the histamine hazard, as they do not include a requirement to maintain harvest vessel records and check internal temperatures or perform histamine testing with internal temperature checks for products received directly from the fishermen.

The [REDACTED] HACCP plan for the scombroid species you import does not list the critical control points of pre and post processing storage for controlling the food safety hazard of histamine.

Domestic

You must have a HACCP plan that lists the critical control points, to comply with 21 CFR 123.6(c)(2). However, your firm's HACCP plan for fin fish does not list the critical control points of pre and post processing storage for controlling the food safety hazard of histamine formation.

You must have a HACCP plan that lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plan for fin fish lists critical limits of maintaining a supplier's certificate of testing and a certificate of guarantee at the receiving critical control point that are not adequate to control the histamine formation hazard.

You must have a HACCP plan that lists monitoring procedures for each critical control point, to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan for fin fish lists monitoring procedures at the receiving critical control point that are not adequate to control the histamine formation hazard.

The above identified deviations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that all seafood products processed and distributed by your firm are in compliance with the Act and all requirements of the federal regulations.

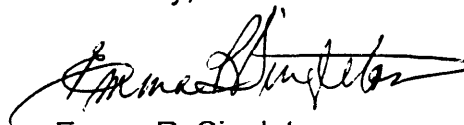
You should take prompt measures to correct these deviations. Failure to promptly correct the deviations noted may result in regulatory action without further notice. Such action includes seizure and/or injunction. In addition, FDA may detain your imported seafood products without examination. Under such conditions, FDA will not issue any Certificates for Export or European Union Health Certificates for any of the affected fish and fishery products processed at your facility.

Please notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct these violations, including an explanation of each step taken to prevent their reoccurrence. Your response should include copies of any available documentation demonstrating that corrections have been made. If corrections cannot be completed with 15 working days, state the reason for the delay and the time frame within which the corrections will be completed.

Please send your reply to the Food and Drug Administration, Attention: Ken Hester, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida 32751. If you have questions regarding implementation of the HACCP Regulations, you may contact Ken Hester at (407) 475-4730 for answers and/or direction towards guidance and sources of training in achieving compliance.

We look forward to working with you to achieve a successful HACCP program.

Sincerely,

A handwritten signature in black ink, appearing to read "Emma R. Singleton", with a long horizontal flourish extending to the right.

Emma R. Singleton,
Director, Florida District